SAMSUNG BIOEPIS

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By Electronic Submission

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Comments on Benefit-Risk Considerations for Product Quality Assessments; Draft Guidance for Industry; Availability [Docket No. FDA-2022-D-0168]

Dear Madam/Sir,

Samsung Bioepis, established in 2012, is committed to enabling healthcare be more accessible by making affordable safe, effective quality biologics. Through innovations in product development and a firm commitment to quality, Samsung Bioepis will become a leading biopharmaceutical company. We continue to advance a broad pipeline of biosimilar candidates that cover a spectrum of therapeutic areas, including immunology, oncology, ophthalmology, hematology and endocrinology. We have biologics approved in a number of highly regulated markets and have made products within our portfolio commercially available since 2016.

Samsung Bioepis greatly appreciates the FDA's efforts to provide clearer insight as to how FDA assesses risk, sources of uncertainty, and possible mitigation strategies for a product quality-related issue and how those considerations can inform FDA's understanding of the potential effect on a product. How benefit-risk principles are applied by FDA when conducting product quality-related assessments using chemistry, manufacturing, and controls (CMC) information submitted for FDA review, and how unresolved product quality issues may be addressed in the context of regulatory decision-making are discussed in this draft guidance for industry "Benefit-Risk Considerations for Product Quality Assessment".

While the determination of a drug's overall clinical benefit(s) is outside the scope of the product quality assessment and as such is not addressed, the draft guidance lists the following as part of the assessment of benefit for product quality issue: 1) whether a greater understanding of the patient population and diseases for which the product will be used can be gained, 2) whether the drug addresses an unmet medical need, and 3) whether potential sources of product quality risk that, if unmitigated, could result in a risk to the patient can be identified.

As a biosimilar sponsor, we ask the FDA to also consider the overall benefit of biosimilars to the healthcare system as part of the benefit-risk considerations for product quality assessment. As outlined in the Biologics Price Competition and Innovation Act of 2009 (BPCIA)

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enacted as Title VII of the Patient Protection an Affordable Care Act, the new regulatory pathway for biosimilar was created with the goal of reducing the cost of health care and improving how patient receive care which includes greater access. Biosimilars can improve broader patient access to biologics through improved affordability (which may be cost savings to various stakeholders) and this in turn enables earlier treatment in some instances of chronic and debilitating diseases in a manner that has the potential to significantly improve overall treatment outcomes. In a recent report[1], US savings from biosimilars was projected to be $38.4 billion or 5.9% of projected total U.S. spending from 2021 to 2025 due to the new downward pressure on reference biologic prices and new biosimilar entry. The cost saving procured by biosimilars can be allocated to other aspects of patient care, and these may well include the elements specified about such as the nature of the patient populations to which these medicines become available, their unmet medical needs and the quality of the products that they can expect to be able to access. Therefore, we believe that this unique benefit of biosimilars should also be considered as part of the benefit-risk considerations for product quality assessment. Quality should be fit-for-purpose and consistent across all FDA regulated products, but also support access through affordability by all patients who can benefit. Indeed, timely access is an unmet medical need especially for fatal diseases (e.g. oncology) but also for progressive ones (e.g. immunology, ophthalmology).

Overall, the guidance provides valuable information that the industry can reference when performing product quality assessment and on what to expect when an unresolved quality issue remains. Once again, we thank for the opportunity to comment on the Draft Guidance for Industry, *Benefit-Risk Considerations for Product Quality Assessment*, and look forward to its continued evolution with all the stakeholders impacted.

If you have any questions regarding the above comments or need additional information, please do not hesitate to contact Byoung In Jung, Vice President of Regulatory Affairs Team, by email at byoungin.jung@samsung.com.

Sincerely,

Byoung In Jung

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[1] Mulcahy A. et al. Projected US Savings From Biosimilars, 2021-2025. Am J Manag Care. 2022;28(7):In Press https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025